UNITED STATES DISTRICT COURT

DISTRICT OF CONNECTICUT

THE STATE OF CONNECTICUT; THE STATE OF ALASKA; THE STATE OF ARIZONA; THE STATE OF ARKANSAS; THE STATE OF CALIFORNIA; THE STATE OF COLORADO; THE STATE OF DELAWARE; THE DISTRICT OF COLUMBIA; THE STATE OF FLORIDA; THE STATE OF HAWAII; THE STATE OF IDAHO; THE STATE OF ILLINOIS; THE STATE OF INDIANA; THE STATE OF IOWA; THE STATE OF KANSAS; THE COMMONWEALTH OF KENTUCKY; THE STATE OF LOUISIANA; THE STATE OF MAINE; THE STATE OF MARYLAND; THE COMMONWEALTH OF MASSACHUSETTS; THE STATE OF MICHIGAN; THE STATE OF MINNESOTA; THE STATE OF MISSISSIPPI; THE STATE OF MISSOURI; THE STATE OF MONTANA; THE STATE OF NEBRASKA; THE STATE OF NEVADA; THE STATE OF NEW HAMPSHIRE; THE STATE OF NEW JERSEY; THE STATE OF NEW MEXICO; THE STATE OF NEW YORK; THE STATE OF NORTH CAROLINA; THE STATE OF NORTH DAKOTA; THE STATE OF OHIO; THE STATE OF OKLAHOMA; THE STATE OF OREGON; THE COMMONWEALTH OF PENNSYLVANIA; THE COMMONWEALTH OF PUERTO RICO; THE STATE OF RHODE ISLAND; THE STATE OF SOUTH CAROLINA; THE STATE OF TENNESSEE; THE STATE OF UTAH; THE STATE OF VERMONT; THE COMMONWEALTH OF VIRGINIA; THE STATE OF WASHINGTON; THE STATE OF WEST VIRGINIA; THE STATE OF WISCONSIN; and THE STATE OF WYOMING v. AUROBINDO PHARMA USA, INC.; ACTAVIS HOLDCO US, INC.; ACTAVIS PHARMA, INC.; APOTEX CORP.; ASCEND LABORATORIES, LLC; CITRON PHARMA, LLC; DR. REDDY'S	No. 3:16-cv-02056 (MPS)

LABORATORIES, INC.; EMCURE PHARMACEUTICALS, LTD; GLENMARK PHARMACEUTICALS INC., USA; HERITAGE PHARMACEUTICALS, INC.; LANNETT COMPANY, INC.; RAJIV MALIK; MAYNE PHARMA (USA), INC.; SATISH MEHTA; MYLAN PHARMACEUTICALS INC.; TEVA PHARMACEUTICALS USA, INC.; SANDOZ, INC.; SUN PHARMACEUTICAL INDUSTRIES, INC.; and ZYDUS PHARMACEUTICALS (USA), INC.

RULING ON MOTIONS TO AMEND AND JOIN PARTIES

The Plaintiffs (the "States") have filed motions to amend the operative complaints in two of the three cases brought by State and territorial attorneys general against makers of generic drugs that allege violations of federal and state antitrust and consumer protection statutes. The two cases are 16cv2056 (the "Heritage case") and 19cv710 (the "Teva case"). For the reasons stated in this ruling and in comments I made during oral argument held on November 18, 2024, the motions to amend (ECF Nos. 475 and 615 in 16cv2056) are DENIED to the extent those motions relate to the Heritage complaint, and the motions to amend (ECF Nos. 203, 405, and 406 in 19cv710) are GRANTED to the extent those motions relate to the Teva complaint. I assume familiarity with the motions, briefs, and attachments, the November 18 oral argument, and the record of this case and the MDL case. I provide only enough reasoning in this ruling to enable counsel to understand my rationale.

Essentially, I split the ruling between the two cases because the MDL court set a deadline—long since passed—for amending the complaint in the Heritage case but did not do so in the Teva case. Although Rule 15 of the Federal Rules provides for a "liberal" amendment policy, the more rigorous "good cause" standard applies to amendments made after a deadline set by the Court under Rule 16. These different standards drive this ruling.

I. Heritage Case, 16cv2056

Pretrial Order No. 61 (E.D. Pa., 2:16-md-2724-CMR, ECF No. 775) ("PTO 61"), which applies to the Heritage case, was issued on November 20, 2018, and includes the following as its first substantive paragraph:

> I. SCHEDULE FOR AMENDMENTS TO COMPLAINTS
>
> 1. Any amendment to any currently outstanding complaint must be made on or before **December 21, 2018**. No further amendments will be permitted after that date except [in circumstances following rulings on motions to dismiss that do not apply here] or as permitted by the Federal Rules of Civil Procedure or Court Order.

While the States argue that PTO 61 is not a formal Rule 16 scheduling order and while it is missing one element of such an order in that it does not set a deadline for "complet[ing] discovery," Fed. R. Civ. P. 16(b)(3), I find that it is a Rule 16 scheduling order. Rule 16 is designed to be a flexible tool that may be adapted to the needs of a particular case, as is apparent from its provisions. *See* Rule 16(a), 16(b)(3)(B), 16(c)(2). And, so, though PTO 61 is not denominated a "scheduling order" and does not address discovery deadlines, the plain language quoted above makes clear that the MDL court intended that PTO 61 be a firm deadline for amendments to complaints, and the passage of that deadline means that Rule 16's "good cause" standard applies.

The States also argue that the phrase, "as permitted by the Federal Rules of Civil Procedure," allows them to avail themselves of the liberal amendment policy in Rule 15. I disagree. PTO 61 refers to "the Federal Rules" as a whole, a formulation that takes account of situations in which two or more rules might be implicated but, because of the language of the Rules or the way courts have interpreted them, one of the Rules takes priority over another. As noted, that is the situation here, i.e., because the court-set deadline for amending the complaint

expired six years ago, the liberal amendment policy of Rule 15, although still part of the analysis, must yield to the more rigorous good cause standard of Rule 16.

The States argue that, even if Rule 16 applies, they have satisfied the "good cause" standard, because they have shown, as they must, that they have exercised diligence in seeking the proposed amendments. In the Heritage case, the States are seeking only one amendment: joining as new defendants and adding allegations against Novartis AG ("Novartis") and Sandoz AG. I do not find that they have shown adequate diligence in seeking this amendment for the following reasons:

1. The Defendants have shown that much of the information on which the States relied in making the new allegations about Novartis and Sandoz AG in the proposed amended complaint comes from (or was available in) documents produced by the Defendants years ago in the MDL proceeding. *See* ECF No. 476-3 at 2. Although the States point to more recent events as the source of their new allegations—including a prospectus detailing the spinoff of Sandoz AG and Sandoz, Inc. and a Rule 30(b)(6) deposition of a Sandoz designee in August 2023—the Defendants have shown that some of the private plaintiffs in the MDL proceeding, who have made similar motions to amend now pending before the MDL Court, make essentially the same new allegations citing documents produced years ago in the MDL proceeding.

2. As the Defendants also note, there were also other sources of information available to the States before August 2023 from which the States likely could have derived much of the information forming the basis for their new allegations about Novartis and

Sandoz AG. The spinoff was publicly announced in August 2022 and, although details were apparently not provided until the filing of the prospectus a year later, the States could have called upon the former Sandoz, Inc. employees with whom they have long had cooperation agreements to provide more information about any involvement by Novartis and Sandoz AG in the conduct alleged in the complaint. These employees were involved in the alleged conduct described in the complaint and likely would have been in a good position to provide information about the degree to which Sandoz, Inc.'s parents and affiliates, including Novartis and Sandoz AG, influenced that conduct, i.e., the same information that forms the basis of the States' proposed new allegations against these companies. The States likely could have obtained that information well before August 2023.

3. Even after the August 2023 prospectus and Rule 30(b)(6) deposition, the States waited seven months to file their motion to amend. Some of the plaintiffs in the MDL court sought this relief more promptly—as early as January 2024. While the Court would not rely on the delay between August 2023 and the filing of the motions on April 1, 2024 alone as a basis for finding insufficient diligence, that time frame does not suggest that the States have shown the dispatch warranted for proposing amendments that will inevitably cause delays in what is already an old case.

4. Finally, after receiving scheduling proposals from the parties and holding a status conference on August 14, 2024, to discuss them, I set what I thought would be the final schedule for completing discovery and for filing *Daubert* and dispositive motions. (ECF No. 606.) While the motions to amend that are the subject of this

ruling were already pending by then, it is noteworthy that no one mentioned at the status conference that those motions could seriously disrupt the schedule we were discussing. Indeed, no one mentioned the motions to amend at all at the status conference. Again, while I would not rely on this alone in finding insufficient diligence, it would have been more consistent with Rule 1 of the Federal Rules to raise at the status conference (or in the scheduling proposals) that there was a need to consider that the schedule might have to be substantially modified if I were to grant the pending motions to amend.

II. Teva Case, 19cv710

I do not find that MDL Pretrial Order No. 153 (E.D. Pa., 2:16-md-2724-CMR, ECF No. 1648) ("PTO 153"), which governs the Teva case, sets a deadline for amending the Teva complaint. That order includes language making clear that it does not apply to the proposed amendments, which were filed on April 1, 2024. Pretrial Order No. 153 paras. 1 & 3 ("This Order applies to . . . motions for leave to amend . . . so long as the . . . motion for leave to amend was filed on or before December 15, 2020. . . . Any [other] amendment or proposed amendment . . . is beyond the scope of this Order."). So Rule 16 is inapplicable, leaving Rule 15's liberal amendment policy to govern the analysis.

Under Rule 15, the court "should" freely grant leave to amend "when justice so requires," Fed. R. Civ. P. 15(a)(2), unless the court finds futility, bad faith, undue delay, or undue prejudice to the opposing party. *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007). With respect to the Teva complaint, the States seek to add not only Novartis and Sandoz AG and the new allegations associated with them but also to (1) add California as a plaintiff, (2) add

individual defendants to the claims brought by New York, and (3) "amend[] and clarif[y] factual allegations to conform with discovery conducted in this case." ECF No. 203 at 2.

Although the parties make arguments on this point, I do not find that it would be productive to consider "futility" in any detail at this stage. The new allegations in the proposed new Teva complaint are not so obviously insufficient that I would find them "futile" at this stage, which is in any event not an ideal stage to consider the adequacy of allegations. This ruling is without prejudice to Novartis's and Sandoz AG's filing motions to dismiss, and I will consider those motions thoroughly after full briefing.

The Defendants have made no plausible argument that the States have acted in "bad faith" in seeking the proposed amendments.

That leaves "undue delay" and "undue prejudice." While there has been delay and there will be some prejudice to the Defendants if the new Teva complaint is allowed, I do not find either the delay or the prejudice to be "undue." With respect to the new allegations against Novartis and Sandoz AG, while, as noted, the States likely had enough—or had access to enough—information to make these allegations earlier, declining to dig deeper to find the information sooner or even waiting until the information was confirmed or better developed—through the August 2023 prospectus and Rule 30(b)(6) deposition—does not amount to "undue" delay under Rule 15's liberal standard. Nor does the seven-month delay between those events and the filing of the motion. As for "undue prejudice," the most significant prejudice to Defendants will result from the likely need to amend the scheduling order to accommodate the addition of Novartis and Sandoz AG. This will involve allowing time principally for discovery related to the agency and veil-piercing-type allegations in the new complaint. I am not convinced at this stage by the Defendants' (and Sandoz AG's) arguments that adding these two

new parties would warrant reopening discovery more broadly on the substantive antitrust allegations in the complaint, because Sandoz, Inc., which has long been a party and was a wholly subsidiary of Novartis and an affiliate of Sandoz AG until the recent spinoff, had every incentive to take and defend the same discovery that will affect the liability of its then-parent and affiliate. Nonetheless, I do not exclude the possibility that there will be some areas where discovery will need to go beyond just the derivative-liability allegations. Still, some additional discovery is usually necessary whenever a new party is added to a case, and here it should mostly be limited to the derivative-liability allegations. So, I do not find the prejudice from adding the Novartis/ Sandoz AG allegations to be "undue."

Nor was there "undue" delay in seeking the other proposed additions to the Teva complaint, and allowing them will not cause "undue" prejudice. The addition of California—though it certainly could have been done earlier and would not satisfy the diligence test if it applied—is not "undue delay." While California was on notice that its agencies might be left out of some of the related class actions in the MDL proceeding well before it sought to join the Teva case, it did receive a more certain indication of that exclusion when the motion for class certification was filed in the MDL proceeding in November 2023. And adding California will not cause material prejudice for the reasons I stated during the argument. While it could, as the Defendants argued, increase the costs of expert discovery, that would be true regardless of when California sought to join the case. It is also difficult to predict exactly how the addition of a single plaintiff to such a large case will ultimately affect costs. Finally, the proposed addition by New York of the individual defendants—though it too could have done much earlier—is a relatively insignificant change and will lead to no new discovery and no new cost burdens on any party. The Defendants did not object in their briefs or at oral argument to the addition of the

"clarifying" allegations, and so I do not address those.

III. Conclusion

For the reasons stated above and at the oral argument, I deny ECF Nos. 475 and 615 in the Heritage case, 16cv2056, and I grant ECF Nos. 203, 405, and 406 in the Teva case, 19cv710. In the Heritage case, the operative complaint will remain ECF No. 473. In the Teva case, the States shall file and serve on the new proposed defendants forthwith the proposed amended complaint.

Two additional points. First, the parties in the Teva case shall meet and confer within 21 days of the filing of an appearance by counsel for Novartis and Sandoz AG about any proposed amendments to the scheduling order the Court adopted in August. ECF No. 384. Within 7 days of their meet and confer, they shall file a joint proposed revised scheduling order or, if they cannot agree, separate proposals in the same joint filing. Second, the parties in the Heritage and Teva cases shall meet and confer within 21 days of this ruling and shall, within 7 days thereafter, file a joint statement in each case indicating whether I should revisit my August 15, 2024 order designating the Teva case as "Case Number 1" and the Heritage case as "Case Number 2." Heritage ECF No. 605; Teva ECF No. 383. Specifically, I am considering whether, in light of this ruling, I should put Heritage on the faster track and Teva on the slower track. The parties should address this question in their joint filing.

IT IS SO ORDERED.

/s/
Michael P. Shea, U.S.D.J

Hartford, Connecticut
November 19, 2024